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Remarks

Restriction

Applicants acknowledge their election to prosecute claims 1-21 pursuant the restriction requirement of December 5, 2006. Accordingly, non-elected claims 22-28 have been canceled.

Amendments

Non-elected claims 22-28 have been canceled, without prejudice, as discussed above.

Independent claims 1 and 18 have been amended, without prejudice, to change formal matters.

Claims 1-21 remain in the application for reconsideration.

Summary of the Invention

Before discussing the rejection on the merits, it will be helpful to briefly review Applicants' invention.

In one aspect of the invention, as set forth in both independent claims 1 and 18, a stent comprises a tubular member having an interior surface and an exterior surface, with a region of at least one of the ***surfaces*** being ***hydrophobic***. The ***hydrophobic surface*** region is provided with an array of microstructures or nanostructures that covers first portions of the surface but leaves second portions exposed in the interstices of the array. These structures cause the region to have a ***dynamically controllable*** hydrophobicity.

In one embodiment, a control device, which is affixed to the tubular member, varies the surface hydrophobicity of the region (claim 2; claim 18, lines 24-25). In another embodiment, which is particularly applicable to the delivery of a medicinal substance (e.g., a chemically active agent such as pharmacological agent or drug) to fluids in body vessels, the stent also includes such a medicinal substance that adheres to the exposed portions until the control device alters the hydrophobicity of the region and causes the substance to be released into the body fluid in contact with the stent (claims 5-7; claim 18, lines -23-25). In still another embodiment, the control device is remotely actuated from a source located external to the body (claim 4; claim 18,

line 26).

In still another aspect of the invention, the hydrophobic surface region is ***tiled***; that is, divided into at least first and second zones whose surface hydrophobicity is separately controllable, so that, for example, chemically active (e.g., medicinal) substances adhered to those zones may be selectively released (claim 9; claim 19). The same substances, with the same or different dose, may be adhered to the first and second zones (claim 10; claim 20), or different substances may be adhered to the first and second zones (claim 11; claim 21).

Claim Rejections – 35 USC §102

Claims 1-8, 12-13 and 18-20 have been rejected under 35 USC §102(b) as being anticipated by S. R. Bailey ***et al.***, International Application Publication No. WO 02/064019, which was published on August 22, 2002 (hereinafter ***Bailey***).

Claims 1-2, 5-7 and 9-11 have been rejected under 35 USC §102(e) as being anticipated by C. Momma ***et al.***, US Patent Application Publication No. 2005/0027350, which was published on February 3, 2005 based on an application filed on July 30, 2003 (hereinafter ***Momma***).

Claims 1-2, 5-7 and 15-17 have been rejected under 35 USC §102(e) as being anticipated by V. P. Shastri ***et al.***, US Patent Application Publication No. 2004/0115239, which was published on July 17, 2004 based on an application filed on September 22, 2003 (hereinafter ***Shastri***).

Claims 1 and 14 have been rejected under 35 USC §102(e) as being anticipated by N. M. Roth, US Patent No. 6,527,919 (hereinafter ***Roth***). Given that this patent issued on March 4, 2003, more than one year prior to Applicants' filing date of March 11, 2004, we assume that the Examiner intended this rejection to be predicated on Section 102(b), not Section 102(e).

These rejections are respectfully traversed for any one or more of the reasons set forth below.

(1) **Anticipation:** The law of anticipation under Section 102 is clear, as set forth in MPEP 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053

(Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ...claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). ***Each and every element*** of Applicants' claims is ***not*** found in either Bailey, or Momma, or Shastri, or Roth, as discussed below.

(2) **Surface Hydrophobicity:** In Applicants' stent the hydrophobicity of a ***surface*** of a tubular member is ***dynamically*** controlled (claims 1 and 18). Applicant teaches that this type of surface hydrophobicity relates to the surface tension (specification, page 5, line 21) of a low-energy surface that is characterized by a high contact angle (> 90°) to any fluid it contacts (specification, page 7, lines 3-4). Importantly, the desired surface hydrophobicity is ***not inherent*** in the typical materials (e.g., metals) used to make stents. To this end, Applicants illustratively coat the tubular member with a hydrophobic layer 67 (FIG. 3) comprising illustratively a polymer or Teflon (specification, page 7, lines 5-8). In contrast, in the Bailey rejection the Examiner asserts, without providing scientific support, that stent metals are "known to be hydrophobic since metals do ***absorb*** water." First, Bailey (as well as Comma, Shastri and Roth) is totally devoid of any explicit discussion of hydrophobicity. Second, the matter of ***water absorption*** is irrelevant to the phenomenon of surface hydrophobicity. [On the other hand, water absorption may be akin to bulk hydrophobicity, which relates to whether a substance mixes with water (e.g., if an oil and water do not mix, the oil is said to be hydrophobic.)] Surface hydrophobicity is related to surface tension, which in turn is related to ***adsorption***, not absorption. Thus, even if the Examiner is correct that metals do not absorb water, it does not follow that the metal ***surface*** is hydrophobic, as that term in used in claims 1 and 18.

(3) **Dynamically Controllable Hydrophobicity-General:** Applicants' invention requires that the surface hydrophobicity is ***dynamically controlled*** (claim 1, lines 6-7; claim 18, lines 20-22). To this end, various embodiments of Applicants' invention include an array of nanostructures (or microstructures; claim 1, lines 5; claim 18, lines 20-21) in a first portion of the surface and a control device affixed to the tubular member for varying the hydrophobicity (claim 2; claim 7; claim 18, lines 24-26).

Even assuming, ***arguendo***, that the references relate to surface hydrophobicity, none describes the dynamic control of that hydrophobicity.

(4) **Dynamically Controllable Hydrophobicity-Bailey:** In Bailey, the Examiner states "The stent has a dynamic controlled hydrophobicity as it detects blood flow, page 10, lines 4-11, page 19." However, Bailey merely describes an array of U-shaped cantilever members disposed on the exterior surface of a stent and responsive to a parameter being sensed (e.g., blood pressure). The positions of the cantilever members (on-raised; off-co-planar; page 17, lines 1-11) change depending on the stress/strain applied thereto (page 18, lines 16-17) and thus provide a quantitative indication of the parameter being sensed. In order to detect the positions of the cantilever members (page 19, line 31 ***et seq.***), they may be exposed to external energy, which returns a signal representative of the number and position of the members. Clearly, the external source reads information from the array of members, but does ***not control*** the hydrophobicity of the surface on which the array is located. Bailey simply provides no teaching that the array of cantilever members causes the stent surface to have a "dynamically controlled hydrophobicity," as required by claims 1 and 18. The mere fact that Bailey's stent "detects blood flow" is not to the contrary.

(5) **Nanostructure/Microstructure:** Claims 1 and 18 call for an array of "microstructures or nanostructures," which cause the surface region to have a "dynamically controllable hydrophobicity." Applicants specifically predefine such a "nanostructure" as having at least one dimension of less than one micrometer, and a "microstructure" is a predefined structure having at least one dimension of less than one millimeter (page 4, lines21-24). In contrast, Bailey teaches no dimensions for the U-shaped cantilevers 22 (FIG. 3) that constitute his array. However, given the size depicted by Bailey relative to the stent, one of ordinary skill in the art would surely expect that these cantilevers appear to be ***macrostructures***, not microstructures and surely not nanostructures as defined by Applicants.

(6) **Variable Penetration of Interstices:** Claim 8 calls for a control device that varies

the "penetration of the interstices of said array by said fluid, thereby causing release of said agent or drug into said fluid." This feature has not been addressed by the Examiner in his rejection of claim 8 in view of Bailey. Consequently, a prima facie case of anticipation has not been established. For the record, however, Bailey is totally devoid of any teaching of this control feature, which enables Applicants' array to control surface hydrophobicity and, in turn, the release of agents/drugs located in the interstices.

(7) **Dynamically Controllable Hydrophobicity-Momma:** The Examiner asserts that FIG. 2 of Momma "shows a stent body 42 that includes an array (*sic*) microstructures 38 and control device in the form of a membrane 46 to vary hydrophobicity." First, there is no evidence that Momma's array of raised micro-channels 38 affect surface hydrophobicity. Second, element 46 is merely a biodegradable cover layer that releases underlying active substance 44 into blood vessel media 22. Momma provides no teaching that cover layer 46 has any effect, no less control, of surface hydrophobicity, as required by claim 1.

(8) **Dynamically Controllable Hydrophobicity-Shastri:** The Examiner makes no assertions that Shastri in any way describes the dynamic control of surface hydrophobicity of a stent, as required by claim 1. Instead, he merely points to Shastri's disclosure that "fibers or particles of nanosize" are deposited on the surface of an implant and that the nano-material can be silicon. First, there is no evidence that Shastri's particles affect surface hydrophobicity. Second, the fact that the particles may be made of silicon is irrelevant, since a silicon surface without more is not hydrophobic, as that term is used in the art and set forth in Applicants' specification. (Recall that Applicants' silicon nanostructure is covered with, for example, a polymer or Teflon layer to render the surface hydrophobic.) Third, the Examiner references paragraphs 75, 79 and 84 of Shastri to show that "chemically active substances can be used on the devices with control devices (polymer materials)," but there is no evidence in these paragraphs that any such device controls the surface hydrophobicity of Shastri's deposited particle layer.

(9) **Dynamically Controllable Hydrophobicity-Roth:** The Examiner asserts that Roth's stent 1 includes an array of microstructures, and that, since the stent is made of metal, it is ***inherently*** hydrophobic. First, there is no evidence that Roth's microstructures (i.e., perforations 5) are capable of dynamically controlling the surface hydrophobicity of his stent 1, as required by claim 1. Second, a metal ***surface*** is not inherently hydrophobic, as discussed in paragraphs (2) and (3) above.

(10) **Tiled Hydrophobic Surface:** Claims 9 and 19 recited a stent design in which the array of nanostructures/microstructures covers first portions of the stent surface, and second portions (e.g., the interstices of the array) remain exposed. This exposed portion is ***tiled*** in this embodiment of the invention; that is, divided into electrically isolated first and second zones, which have chemically active substances adhered thereto. The control device actuates the release of the substances from the zones. In this regard, the Examiner has cited Bailey against claim 19 and Momma against claim 9. However, in applying Bailey to claim 19, the Examiner does not explicitly address the separate control of tiled, isolated surface zones leading to the controlled release of substances from predetermined zones. Thus, a ***prima facie*** case of anticipation of claim 19 in view of Bailey has not been made out. Likewise, what Momma teaches in this regard is quite different from Applicants' invention, as defined by claim 9. Momma's approach to the release of multiple, different substances is evident from FIG. 2, which shows two active substances 52, 54 ***stacked*** on top of one another at the ***same*** implantation site. The upper active substance 54 is covered by a biodegradable layer 46, and the lower active substance 52 is covered by a biodegradable layer 50, which also separates the two active substance layers 52, 54 from one another. Over time the upper cover layer 46 biodegrades releasing upper active substance 54. Later, the lower cover layer 50 biodegrades releasing lower active substance 52. Note, the biodegradation of cover layers 46, 50 is a ***passive*** function; it not ***dynamically*** controlled by an ***ex vivo*** source as required by claim 9. In addition, claim 9 requires that the ***exposed portion of the hydrophobic surface is electrically isolated into first and second spatial zones*** containing a chemically

active substance (i.e., the surface is ***tiled*** into separately controllable zones), and the control device is capable of causing separate release of the substances from the first and second zones at different times. Clearly, for each micro-channel 38 Momma's stacked, active substances are disposed in/above the ***same zone of the surface***, not in ***different*** surface zones, and Momma's control of the release of the substances is passive not dynamic.

In view of the foregoing it is respectfully submitted that claims 1-21 are not anticipated by Bailey, Momma, Shastri or Roth.

Claim Rejections – 35 USC 103

Claim 21 has been rejected under 35 USC 103(a) as being unpatentable over Bailey in view of Momma. However, this rejection is predicated on the notion that all of the limitations of independent claim 21 are taught by Bailey except for "different substances to be released into the implantation site."

This rejection is respectfully traversed. As argued above with reference to the Section 102 rejections based on Bailey, which arguments are incorporated herein by reference, claim 18 includes several fundamental, patentably distinguishing features (including those related to the dynamic control of surface hydrophobicity) that are not disclosed by Bailey. Moreover, these deficiencies are not remedied by Momma. Accordingly, claim 21, which depends from claim 18, is likewise patentable.

In addition, however, even assuming, ***arguendo***, that the Examiner's position on Bailey is correct, his further reliance on Momma is misplaced. More specifically, the Examiner makes the following assertions:

> Momma et al. teach different medicinal substances can be utilized to deliver to the implantation site for different purposes, paragraphs 21, 45. It would have been obvious...to incorporate different drugs on the stent as taught by Momma et al. in the stent of Bailey...

What Momma teaches in this regard, however, is quite different from Applicants' invention. Momma's approach to the release of multiple, different substances is evident from FIG. 2, which

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Conclusion

In view of the foregoing, reconsideration of claims 1-21, and passage of this application to issue, are hereby respectfully requested. If during the consideration of this paper, the Examiner believes that resolution of the issues raised will be facilitated by further discussion, she is urged to contact the undersigned attorney at 610-691-7710 (voice) or 610-691-8434 (fax).

Respectfully,

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ARTIFACT OF FACSIMILE MACHINE

OF M. J. URBANO